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EDITORIAL COMMENT

Balancing Optimal Outcomes With Access to Care

It Can Be Done!*

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Providing optimal access to care for complex medical procedures frequently bumps up against the inconvenient reality of the relationship between procedural volumes and the outcomes achieved. This volume-outcome relationship has been extensively studied and documented to be present on both a hospital and individual operator basis for complex surgical procedures (1). As a general rule, the more complex the procedure, the more that experience and the number performed matter. The experience gained from repeated performance is not limited to just the technical expertise of performing the procedure, but more holistically applies to all aspects of the health care ecosystem in which the procedure is performed. This includes prompt timely access to care, appropriate patient selection, post-procedure and post-discharge care, and follow-up.

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With this background in mind, in this issue of *JACC: Cardiovascular Interventions,* Stub et al. (2) from British Columbia have published the outcomes of a regional system of care for transcatheter aortic valve replacement (TAVR) in their province. The study was led by Dr. Webb, a pioneer of this catheter-based approach for treating elderly, inoperable, and high surgical-risk patients with severe aortic stenosis (3). He performed the first procedure by a retrograde approach from the femoral artery in Vancouver in 2006, and for the next 6 years, all patients undergoing the procedure in British Columbia were treated in a single center. However, as with most new procedures introduced into medicine, incremental improvements in devices and techniques occur, learning curves are surmounted, and the procedures become more patient and operator friendly. As a consequence, the treatment can potentially be expanded to a wider group of patients in more diverse clinical settings. Therefore, in 2012, the British Columbia Provincial Health Services Authority established a province-wide transcatheter heart valve program expanding the performance of TAVR to 3 additional sites. While all sites performed selected transfemoral (TF) procedures in native valve aortic stenosis, non-TF approaches, valve-in-valve procedures, and patients deemed to be at high risk were treated only in the reference center. Furthermore, the experienced reference center participated in mentoring, patient selection, and proctoring of the newer sites. The authors present the outcomes achieved over the first 3 years of the program and concluded that the excellent outcomes achieved province-wide demonstrated the potential benefits of a regional system of care.

The authors and the health care authorities in British Columbia are to be congratulated for such a rational and thoughtful approach to health care, balancing first and foremost superior outcomes with expanded access to care, which is a not insignificant issue in this elderly population living across a large geographic area.

One is left however, wanting to know more details on how the program works and why it is successful! How many procedures were performed in the newer lower-volume centers, and what were the outcomes there? Was the Vancouver program really translatable to other sites? What was the evolution of the program in the reference center as the more straightforward, lower-risk patients were treated in other centers? Presumably, a lot of management skills, bureaucratic

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maneuvering, and countless meetings were necessary to implement and maintain the program.

One key question that the authors raise in their limitations is whether this model is expandable to other health care systems in other countries. Indeed, is the development of this regional "hub and spoke" system successful mainly because it is embedded in a universal health care system, or can it be replicated in some form in other health care venues? How much of a role did visionary caregivers and health policy leaders play in bringing all the stakeholders to the table and implementing such a system, and can this paradigm be reproduced elsewhere?

TAVR was introduced commercially in the United States in late 2011 in a manner termed by Ralph Brindis as "rational dispersion" (4). The primary payer of these procedures in the United States, the Centers for Medicare and Medicaid Services, consulted the professional societies, the American College of Cardiology, and the Society of Thoracic Surgeons for advice as to how this new procedure should be integrated into the U.S health care system. The resultant National Coverage Determination set forth criteria that centers and operators were required to meet as a condition of payment (5). It was envisioned that approximately 400 of the 1,600 cardiac catheterization laboratories and 1,200 cardiac surgery programs would qualify. Indeed today, 4 years after introduction, the Society of Thoracic Surgeons/American College of Cardiology TVT (Transcatheter Valve Therapy) Registry reports that over 35,000 procedures have been performed in approximately 400 centers in 49 states, with generally good outcomes and acceptable geographic access to care (6).

So, where do we go from here in the United States, and what can we learn from the British Columbia program that can be implemented in this country? A new report has indicated that there is a volume-outcome relationship with TAVR (7). A current analysis is underway in the TVT Registry to verify this initial report from the National Inpatient sample. Because we do not have a universal health care system in the United States, the British Columbia program cannot be exactly replicated in this country. However, many aspects of it can. For example, the cardiac surgeons and interventional cardiologists in Michigan have long-standing, successful, statewide programs for cardiac surgery and percutaneous coronary intervention. They are now working together on a statewide TAVR program. Although this will not be possible in most states or even most large metropolitan areas, there is an ongoing amalgamation of hospitals regionally into large health care systems that could adopt many of the aspects of the British Columbia regional program. Indeed, a number of these systems, including Dartmouth-Hitchcock Medical Center, the Johns Hopkins Hospital and Health System, and the University of Michigan Health System, have recently announced a "Take the Volume Pledge" campaign (8). In this program, 10 complex surgical procedures would only be performed in hospitals within their system meeting certain volume metrics. One could envision a similar program for TAVR within health care systems or regions where lower-risk TF approaches could be done in regional programs, whereas higher-risk, more complex, non-TF, and valve-in-valve cases would be performed only in hub reference centers under an integrated, programmatic approach, thereby achieving a balance between access to care and quality outcomes.

The clinicians and health policy experts in British Columbia are to be congratulated for their visionary and balanced approach to the introduction of this new lifesaving procedure in a careful manner that provides wide access to care while not compromising the excellent outcomes. One can only hope that this program serves as a bellwether for the implementation of a similar care model in the United States and in other parts of the world.

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